



JFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Draghia-Akli, Ruxandra, et al.

Serial No.: 10/764,818

Filed: 01/28/2004

Group: unknown

For: REDUCING CULLING IN HERD ANIMALS GROWTH HORMONE
RELEASING HORMONE (GHRH)

Commissioner of Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Certificate of Mailing under 37 CFR 1.8: I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on May 19, 2004.

M. Alford

Signature

M. ALFORD

Typed or Printed name of person signing Certificate

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT WITHIN THREE
MONTHS OF FILING OR BEFORE MAILING OF FIRST OFFICE ACTION**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office Action on the merits, which ever event occurs last 37 C.F.R. § 1.97(b).

Respectfully submitted,
JACKSON WALKER L.L.P.

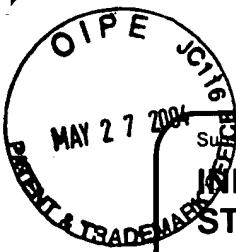
T. Ling Chwang
T. Ling Chwang
Registration No. 33,590

May 19, 2004

Date

JACKSON WALKER L.L.P.
2435 North Central Expressway, Suite 600
Richardson, Texas 75080
Tel: (972) 744-2919
Fax: (972) 744-2909

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of 16 Sheets

Complete if Known

| | |
|----------------------|-------------------------------|
| Application Number | 10/764,818 |
| Filing Date | 01/26/2004 |
| First Named Inventor | Ruxandra Draghia-Akli, et al. |
| Group Art Unit | |
| Examiner Name | |

Attorney Docket Number AVSI-0033 (108328.00170)

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|--|--------------------------------|--|---|
| | | Number - Kind Code ² (if known) | | | |
| 1. | U.S.- 5,847,066 | 08-Dec-98 | Coy et al. | Entire Patent | |
| 2. | U.S.- 5,846,936 | 08-Dec-98 | Felix et al. | Entire Patent | |
| 3. | U.S.- 5,792,747 | 11-Aug-98 | Schally et al. | Entire Patent | |
| 4. | U.S.- 5,776,901 | 07-Jul-98 | Bowers et al. | Entire Patent | |
| 5. | U.S.- 5,756,264 | 26-May-98 | Schwartz et al. | Entire Patent | |
| 6. | U.S.- 5,696,089 | 09-Dec-97 | Felix et al. | Entire Patent | |
| 7. | U.S.- 5,486,505 | 23-Jan-96 | Bowers et al. | Entire Patent | |
| 8. | U.S.- 5,292,721 | 08-Mar-94 | Boyd et al. | Entire Patent | |
| 9. | U.S.- 5,137,872 | 11-Aug-92 | Seely et al. | Entire Patent | |
| 10. | U.S.- 5,134,120 | 28-Jul-92 | Boyd et al. | Entire Patent | |
| 11. | U.S.- 5,084,442 | 28-Jan-92 | Felix et al. | Entire Patent | |
| 12. | U.S.- 5,061,690 | 29-Oct-91 | Kann et al. | Entire Patent | |
| 13. | U.S.- 5,036,045 | 30-Jul-91 | Thorner | Entire Patent | |
| 14. | U.S.- 5,023,322 | 11-Jun-91 | Kovacs et al. | Entire Patent | |
| 15. | U.S.- 4,839,344 | 13-Jun-89 | Bowers et al. | Entire Patent | |
| 16. | U.S.- 4,410,512 | 18-Oct-83 | Bowers et al. | Entire Patent | |
| 17. | U.S.- RE33,699 | 24-Sep-91 | Drengler | Entire Patent | |
| 18. | U.S.- 4,833,166 | 23-May-89 | Grosvenor et al. | Entire Patent | |
| 19. | U.S.- 4,228,158 | 14-Oct-80 | Momany et al. | Entire Patent | |
| 20. | U.S.- 4,228,156 | 14-Oct-80 | Momany et al. | Entire Patent | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|---|--------------------------------|---|--|----------------|
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| | | | | | | |
| | | | | | | |

| | | |
|--------------------|-----------------|--|
| Examiner Signature | Date Considered | |
|--------------------|-----------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | |
|--|---|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | Complete If Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | Application Number | 10/764,818 |
| | | Filing Date | 01/26/2004 |
| | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | Group Art Unit | |
| | | Examiner Name | |
| (use as many sheets as necessary) | | | |
| Sheet | 2 | of | 16 Sheets |
| Attorney Docket Number | | | AVSI-0033 (108328.00170) |

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|---|--------------------------------|---|--|----------------|
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| | | | | | | |
| | | | | | | |

| | | | |
|-------------------------------|--|----------------------------|--|
| Examiner Signature | | Date Considered | |
|-------------------------------|--|----------------------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | | |
|--|---|----|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | Application Number | 10/764,818 |
| (use as many sheets as necessary) | | | Filing Date | 01/26/2004 |
| | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | Group Art Unit | |
| | | | Examiner Name | |
| Sheet | 3 | of | 16 Sheets | Attorney Docket Number |
| AVSI-0033 (108328.00170) | | | | |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|--|-----------------------|---|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 26. | Aihara, H. and J. Miyazaki. 1998. Gene transfer into muscle by electroporation in vivo. Nat. Biotechnol. 16:867-870. | | |
| | 27. | Almendro, N., T. Bellon, C. Rius, P. Lastres, C. Langa, A. Corbi, and C. Bernabeu. 1996. Cloning of the human platelet endothelial cell adhesion molecule-1 promoter and its tissue-specific expression. Structural and functional characterization. J. Immunol. 157:5411-5421. | | |
| | 28. | Aratani, Y., R. Okazaki, and H. Koyama. 1992. End extension repair of introduced targeting vectors mediated by homologous recombination in mammalian cells. Nucleic Acids Res. 20:4795-4801. | | |
| | 29. | Argente, J., J. Pozo, and J. A. Chowen. 1996. The growth hormone axis: control and effects. Hormone Research 45 Suppl 1:9-11. | | |
| | 30. | Auchting, T. L., D. S. Buchanan, C. A. Lents, S. M. Barao, and G. E. Dahl. 2001. Growth hormone response to growth hormone-releasing hormone in beef cows divergently selected for milk production. J. Anim Sci. 79:1295-1300. | | |
| | 31. | Barr, E. and J. M. Leiden. 1991. Systemic delivery of recombinant proteins by genetically modified myoblasts [see comments]. Science 254:1507-1509. | | |
| | 32. | Bercu, B. B. and R. F. Walker. 1997. Growth Hormone Secretagogues In Children With Altered Growth. Acta Paediatrica 86:102-106. | | |
| | 33. | Bettan, M., F. Emmanuel, R. Darteil, J. M. Caillaud, F. Soubrier, P. Delaere, D. Branelec, A. Mahfoudi, N. Duverger, and D. Scherman. 2000. High-level protein secretion into blood circulation after electric pulse-mediated gene transfer into skeletal muscle. Mol. Ther. 2:204-210. | | |
| | 34. | Blethen, S. L. and M. H. MacGillivray. 1997. A risk-benefit assessment of growth hormone use in children. Drug Saf 17:303-316. | | |
| | 35. | Blethen, S. L. and A. C. Rundle. 1996. Slipped capital femoral epiphysis in children treated with growth hormone. A summary of the National Cooperative Growth Study experience. Horm. Res. 46:113-116. | | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | | | |
|--|---|----|-----------|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | | Complete If Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/764,818 |
| | | | | Filing Date | 01/26/2004 |
| | | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 4 | of | 16 Sheets | Attorney Docket Number | AVSI-0033 (108328.00170) |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|--|-----------------------|--|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 36. | Bohlen, P., F. Esch, P. Brazeau, N. Ling, and R. Guillemin. 1983. Isolation and characterization of the porcine hypothalamic growth hormone releasing factor. Biochem. Biophys. Res. Commun. 116:726-734. | | |
| | 37. | Boshart, M., F. Weber, G. Jahn, K. Dorsch-Hasler, B. Fleckenstein, and W. Schaffner. 1985. A very strong enhancer is located upstream of an immediate early gene of human cytomegalovirus. Cell 41:521-530. | | |
| | 38. | Carbonelli, D. L., E. Corley, M. Seigelchifer, and J. Zorzopoulos. 1999. A plasmid vector for isolation of strong promoters in Escherichia coli. FEMS Microbiol. Lett. 177:75-82. | | |
| | 39. | Chandler, S. D., A. Mayeda, J. M. Yeakley, A. R. Krainer, and X. D. Fu. 1997. RNA splicing specificity determined by the coordinated action of RNA recognition motifs in SR proteins. Proc. Natl. Acad. Sci. U. S. A 94:3596-3601. | | |
| | 40. | Chevalier, R. L., S. Goyal, A. Kim, A. Y. Chang, D. Landau, and D. LeRoith. 2000. Renal tubulointerstitial injury from ureteral obstruction in the neonatal rat is attenuated by IGF-1. Kidney Int. 57:882-890. | | |
| | 41. | Chung, C. S., T. D. Etherton, and J. P. Wiggins. 1985. Stimulation of swine growth by porcine growth hormone. J. Anim Sci. 60:118-130. | | |
| | 42. | Corpas, E., S. M. Harman, M. A. Pineyro, R. Roberson, and M. R. Blackman. 1993. Continuous subcutaneous infusions of growth hormone (GH) releasing hormone 1-44 for 14 days increase GH and insulin-like growth factor-I levels in old men. Journal of Clinical Endocrinology & Metabolism 76:134-138. | | |
| | 43. | Dahl, G. E., L. T. Chapin, M. S. Allen, W. M. Moseley, and H. A. Tucker. 1991. Comparison of somatotropin and growth hormone-releasing factor on milk yield, serum hormones, and energy status. J. Dairy Sci. 74:3421-3428. | | |
| | 44. | Dahler, A., R. P. Wade, G. E. Muscat, and M. J. Waters. 1994. Expression vectors encoding human growth hormone (hGH) controlled by human muscle-specific promoters: prospects for regulated production of hGH delivered by myoblast transfer or intravenous injection. Gene 145:305-310. | | |

| | | |
|--------------------|--|-----------------|
| Examiner Signature | | Date Considered |
|--------------------|--|-----------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

| | | | | | |
|-------------------------------|---|----|-----------|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | | Complete if Known | |
| | | | | Application Number | 10/764,818 |
| | | | | Filing Date | 01/26/2004 |
| | | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 5 | of | 16 Sheets | Attorney Docket Number | AVSI-0033 (108328.00170) |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|--|-----------------------|--|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 45. | Dai, B., H. Wu, E. Holthuizen, and P. Singh. 2001. Identification of a novel cis element required for cell density-dependent down-regulation of insulin-like growth factor-2 P3 promoter activity in Caco2 cells. <i>J. Biol. Chem.</i> 276:6937-6944. | | |
| | 46. | Danko, I. and J. A. Wolff. 1994. Direct gene transfer into muscle. [Review]. <i>Vaccine</i> 12:1499-1502. | | |
| | 47. | Darquet, A. M., B. Cameron, P. Wils, D. Scherman, and J. Crouzet. 1997. A new DNA vehicle for nonviral gene delivery: supercoiled minicircle. <i>Gene Ther.</i> 4:1341-1349. | | |
| | 48. | Darquet, A. M., R. Rangara, P. Kreiss, B. Schwartz, S. Naimi, P. Delaere, J. Crouzet, and D. Scherman. 1999. Minicircle: an improved DNA molecule for in vitro and in vivo gene transfer. <i>Gene Ther.</i> 6:209-218. | | |
| | 49. | Davis, H. L., R. G. Whalen, and B. A. Demeneix. 1993. Direct gene transfer into skeletal muscle in vivo: factors affecting efficiency of transfer and stability of expression. <i>Human Gene Therapy</i> 4:151-159. | | |
| | 50. | Dechow, C. D., G. W. Rogers, and J. S. Clay. 2002. Heritability and correlations among body condition score loss, body condition score, production and reproductive performance. <i>J Dairy Sci</i> 85:3062-3070. | | |
| | 51. | Dhawan, J., L. C. Pan, G. K. Pavlath, M. A. Travis, A. M. Lanctot, and H. M. Blau. 1991. Systemic delivery of human growth hormone by injection of genetically engineered myoblasts. <i>Science</i> 254:1509-1512. | | |
| | 52. | Dolnik, V., M. Novotny, and J. Chmelik. 1993. Electromigration behavior of poly-(L-glutamate) conformers in concentrated polyacrylamide gels. <i>Biopolymers</i> 33:1299-1306. | | |
| | 53. | Domecq, J. J., A. L. Skidmore, J. W. Lloyd, and J. B. Kaneene. 1997. Relationship between body condition scores and milk yield in a large dairy herd of high yielding Holstein cows. <i>J Dairy Sci</i> 80:101-112. | | |
| | 54. | Dorsch-Hasler, K., G. M. Keil, F. Weber, M. Jasin, W. Schaffner, and U. H. Koszinowski. 1985. A long and complex enhancer activates transcription of the gene coding for the highly abundant immediate early mRNA in murine cytomegalovirus. <i>Proc. Natl. Acad. Sci. U. S. A</i> 82:8325-8329. | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

| | | | | | |
|--|---|----|-----------|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/764,818 |
| | | | | Filing Date | 01/26/2004 |
| | | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 6 | of | 16 Sheets | Attorney Docket Number | AVSI-0033 (108328.00170) |

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---------------------|-----------------------|---|----------------|
| | 55. | Draghia-Akli, R., M. L. Fiorotto, L. A. Hill, P. B. Malone, D. R. Deaver, and R. J. Schwartz. 1999. Myogenic expression of an injectable protease-resistant growth hormone-releasing hormone augments long-term growth in pigs. Nat. Biotechnol. 17:1179-1183. | |
| | 56. | Draghia-Akli, R., X. G. Li, and R. J. Schwartz. 1997. Enhanced growth by ectopic expression of growth hormone releasing hormone using an injectable myogenic vector. Nat. Biotechnol. 15:1285-1289. | |
| | 57. | Draghia-Akli, R., P. B. Malone, L. A. Hill, K. M. Ellis, R. J. Schwartz, and J. L. Nordstrom. 2002b. Enhanced animal growth via ligand-regulated GHRH myogenic-injectable vectors. FASEB J. 16:426-428. | |
| | 58. | Dubreuil, P., D. Petitclerc, G. Pelletier, P. Gaudreau, C. Farmer, Mowles, TF, and P. Brazeau. 1990. Effect of dose and frequency of administration of a potent analog of human growth hormone-releasing factor on hormone secretion and growth in pigs. Journal of Animal Science 68:1254-1268. | |
| | 59. | Duck, S. C., H. P. Schwarz, G. Costin, R. Rapaport, S. Arslanian, A. Hayek, M. Connors, and J. Jaramillo. 1992. Subcutaneous growth hormone-releasing hormone therapy in growth hormone-deficient children: first year of therapy. Journal of Clinical Endocrinology & Metabolism 75:1115-1120. | |
| | 60. | Esch, F. S., P. Bohlen, N. C. Ling, P. E. Brazeau, W. B. Wehrenberg, M. O. Thorner, M. J. Cronin, and R. Guillemin. 1982. Characterization of a 40 residue peptide from a human pancreatic tumor with growth hormone releasing activity. Biochemical & Biophysical Research Communications 109:152-158. | |
| | 61. | Etherton, T. D., J. P. Wiggins, C. S. Chung, C. M. Evock, J. F. Rebhun, and P. E. Walton. 1986. Stimulation of pig growth performance by porcine growth hormone and growth hormone-releasing factor. Journal of Animal Science 63:1389-1399. | |
| | 62. | Etienne, M., M. Bonneau, G. Kann, and F. Delatang. 1992. Effects of administration of growth hormone-releasing factor to sows during late gestation on growth hormone secretion, reproductive traits, and performance of progeny from birth to 100 kilograms live weight. J Anim Sci 70:2212-2220. | |
| | 63. | Evans, W. S., M. L. Vance, D. L. Kaiser, R. P. Sellers, J. L. Borges, T. R. Downs, L. A. Frohman, J. Rivier, W. Vale, and M. O. Thorner. 1985. Effects of intravenous, subcutaneous, and intranasal administration of growth hormone (GH)-releasing hormone-40 on serum GH concentrations in normal men. Journal of Clinical Endocrinology & Metabolism 61:846-850. | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | | | |
|--|---|----|-----------|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Application Number | 10/764,818 |
| | | | | Filing Date | 01/26/2004 |
| | | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 7 | of | 16 Sheets | Attorney Docket Number | AVSI-0033 (108328.00170) |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|--|-----------------------|--|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 64. | Farmer, C., D. Petitclerc, G. Pelletier, and P. Brazeau. 1992. Lactation performance of sows injected with growth hormone-releasing factor during gestation and(or) lactation. <i>Journal of Animal Science</i> 70:2636-2642. | | |
| | 65. | Farmer, C., S. Robert, and J. J. Matte. 1996. Lactation performance of sows fed a bulky diet during gestation and receiving growth hormone-releasing factor during lactation. <i>J. Anim Sci.</i> 74:1298-1306. | | |
| | 66. | Fewell, J. G., F. MacLaughlin, V. Mehta, M. Gondo, F. Nicol, E. Wilson, and L. C. Smith. 2001. Gene therapy for the treatment of hemophilia B using PINC-formulated plasmid delivered to muscle with electroporation. <i>Mol. Ther.</i> 3:574-583. | | |
| | 67. | Frohman, L. A., T. R. Downs, E. P. Heimer, and A. M. Felix. 1989. Dipeptidylpeptidase IV and trypsin-like enzymatic degradation of human growth hormone-releasing hormone in plasma. <i>J. Clin. Invest.</i> 83:1533-1540. | | |
| | 68. | Frohman, L. A., J. L. Thominet, C. B. Webb, M. L. Vance, H. Uderman, J. Rivier, W. Vale, and M. O. Thorner. 1984. Metabolic clearance and plasma disappearance rates of human pancreatic tumor growth hormone releasing factor in man. <i>J. Clin. Invest.</i> 73:1304-1311. | | |
| | 69. | Fryer, A. D. and D. B. Jacoby. 1993. Effect of inflammatory cell mediators on M2 muscarinic receptors in the lungs. <i>Life Sci.</i> 52:529-536. | | |
| | 70. | Gehl, J., T. Skovsgaard, and L. M. Mir. 1998. Enhancement of cytotoxicity by electroporation: an improved method for screening drugs. <i>Anticancer Drugs</i> 9:319-325. | | |
| | 71. | Gehl, J., T. H. Sorensen, K. Nielsen, P. Raskmark, S. L. Nielsen, T. Skovsgaard, and L. M. Mir. 1999. In vivo electroporation of skeletal muscle: threshold, efficacy and relation to electric field distribution. <i>Biochim. Biophys. Acta</i> 1428:233-240. | | |
| | 72. | German, M., S. Ashcroft, K. Docherty, H. Edlund, T. Edlund, S. Goodison, H. Imura, G. Kennedy, O. Madsen, D. Melloul, and . 1995. The insulin gene promoter. A simplified nomenclature. <i>Diabetes</i> 44:1002-1004. | | |
| | 73. | Gopinath, R. and T. D. Etherton. 1989a. Effects of porcine growth hormone on glucose metabolism of pigs: I. Acute and chronic effects on plasma glucose and insulin status. <i>J. Anim Sci.</i> 67:682-688. | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | | |
|--|---|----|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | Application Number | 10/764,818 |
| (use as many sheets as necessary) | | | Filing Date | 01/26/2004 |
| | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | Group Art Unit | |
| | | | Examiner Name | |
| Sheet | 8 | of | 16 Sheets | Attorney Docket Number |
| AVSI-0033 (108328.00170) | | | | |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|--|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 74. | Gopinath, R. and T. D. Etherton. 1989b. Effects of porcine growth hormone on glucose metabolism of pigs: II. Glucose tolerance, peripheral tissue insulin sensitivity and glucose kinetics. <i>J. Anim Sci.</i> 67:689-697. | | |
| | 75. | Guillemin, R., P. Brazeau, P. Bohlen, F. Esch, N. Ling, and W. B. Wehrenberg. 1982. Growth hormone-releasing factor from a human pancreatic tumor that caused acromegaly. <i>Science</i> 218:585-587. | | |
| | 76. | Hammond, B. G., R. J. Collier, M. A. Miller, M. McGrath, D. L. Hartzell, C. Kotts, and W. Vandaele. 1990. Food safety and pharmacokinetic studies which support a zero (0) meat and milk withdrawal time for use of sometribove in dairy cows. <i>Ann. Rech. Vet.</i> 21 Suppl 1:107S-120S.:107S-120S. | | |
| | 77. | Heller, R., M. J. Jaroszeski, L. F. Glass, J. L. Messina, D. P. Rapaport, R. C. DeConti, N. A. Fenske, R. A. Gilbert, L. M. Mir, and D. S. Reintgen. 1996. Phase I/II trial for the treatment of cutaneous and subcutaneous tumors using electrochemotherapy. <i>Cancer</i> 77:964-971. | | |
| | 78. | Herzog, R. W., J. D. Mount, V. R. Arruda, K. A. High, and C. D. Lothrop, Jr. 2001. Muscle-directed gene transfer and transient immune suppression result in sustained partial correction of canine hemophilia B caused by a null mutation. <i>Mol. Ther.</i> 4:192-200. | | |
| | 79. | Horlick, R. A. and P. A. Benfield. 1989. The upstream muscle-specific enhancer of the rat muscle creatine kinase gene is composed of multiple elements. <i>Mol. Cell Biol.</i> 9:2396-2413. | | |
| | 80. | Inouye, C., P. Remondelli, M. Karin, and S. Elledge. 1994. Isolation of a cDNA encoding a metal response element binding protein using a novel expression cloning procedure: the one hybrid system. <i>DNA Cell Biol.</i> 13:731-742. | | |
| | 81. | Inouye, S., A. Nakazawa, and T. Nakazawa. 1985. Determination of the transcription initiation site and identification of the protein product of the regulatory gene <i>xylR</i> for <i>xyl</i> operons on the <i>TOL</i> plasmid. <i>J. Bacteriol.</i> 163:863-869. | | |
| | 82. | Jardieu, P., R. Clark, D. Mortensen, and K. Dorshkind. 1994. In vivo administration of insulin-like growth factor-I stimulates primary B lymphopoiesis and enhances lymphocyte recovery after bone marrow transplantation. <i>J Immunol.</i> 152:4320-4327. | | |
| | 83. | Jaynes, J. B., J. E. Johnson, J. N. Buskin, C. L. Gartside, and S. D. Hauschka. 1988. The muscle creatine kinase gene is regulated by multiple upstream elements, including a muscle-specific enhancer. <i>Mol. Cell Biol.</i> 8:62-70. | | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

| | | | | | |
|--|---|----|-----------|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Application Number | 10/764,818 |
| | | | | Filing Date | 01/26/2004 |
| | | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 9 | of | 16 Sheets | Attorney Docket Number | AVSI-0033 (108328.00170) |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|--|-----------------------|---|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | |
| | 84. | Kawamoto, T., K. Makino, H. Niwa, H. Sugiyama, S. Kimura, M. Amemura, A. Nakata, and T. Kakunaga. 1988. Identification of the human beta-actin enhancer and its binding factor. Mol. Cell Biol. 8:267-272. | | T ² |
| | 85. | Kawamoto, T., K. Makino, S. Orita, A. Nakata, and T. Kakunaga. 1989. DNA bending and binding factors of the human beta-actin promoter. Nucleic Acids Res. 17:523-537. | | |
| | 86. | Klamut, H. J., L. O. Bosnay-Collins, R. G. Worton, P. N. Ray, and H. L. Davis. 1996. Identification of a transcriptional enhancer within muscle intron 1 of the human dystrophin gene. Hum. Mol. Genet. 5:1599-1606. | | |
| | 87. | Klamut, H. J., S. B. Gangopadhyay, R. G. Worton, and P. N. Ray. 1990. Molecular and functional analysis of the muscle-specific promoter region of the Duchenne muscular dystrophy gene. Mol. Cell Biol. 10:193-205. | | |
| | 88. | Klindt, J., J. T. Yen, F. C. Buonomo, A. J. Roberts, and T. Wise. 1998. Growth, body composition, and endocrine responses to chronic administration of insulin-like growth factor I and(or) porcine growth hormone in pigs. J. Anim Sci. 76:2368-2381. | | |
| | 89. | Kraus, J., M. Woltje, N. Schonwetter, and V. Hollt. 1998. Alternative promoter usage and tissue specific expression of the mouse somatostatin receptor 2 gene. FEBS Lett. 428:165-170. | | |
| | 90. | Lareyre, J. J., T. Z. Thomas, W. L. Zheng, S. Kasper, D. E. Ong, M. C. Orgebin-Crist, and R. J. Matusik. 1999. A 5-kilobase pair promoter fragment of the murine epididymal retinoic acid-binding protein gene drives the tissue-specific, cell-specific, and androgen-regulated expression of a foreign gene in the epididymis of transgenic mice. J. Biol. Chem. 274:8282-8290. | | |
| | 91. | Larsen, P. R., J. W. Harney, and D. D. Moore. 1986. Sequences required for cell-type specific thyroid hormone regulation of rat growth hormone promoter activity. J. Biol. Chem. 261:14373-14376. | | |
| | 92. | Lee, S. H., W. Wang, S. Yajima, P. A. Jose, and M. M. Mouradian. 1997. Tissue-specific promoter usage in the D1A dopamine receptor gene in brain and kidney. DNA Cell Biol. 16:1267-1275. | | |
| | 93. | Lesbordes, J. C., T. Bordet, G. Haase, L. Castelnau-Ptakhine, S. Rouhani, H. Gilgenkrantz, and A. Kahn. 2002. In vivo electrotransfer of the cardiotrophin-1 gene into skeletal muscle slows down progression of motor neuron degeneration in pmn mice. Hum. Mol. Genet. 11:1615-1625. | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

| | | | | |
|--|----|----|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | Application Number | 10/764,818 |
| (use as many sheets as necessary) | | | Filing Date | 01/26/2004 |
| | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | Group Art Unit | |
| | | | Examiner Name | |
| Sheet | 10 | of | 16 Sheets | Attorney Docket Number |
| AVSI-0033 (108328.00170) | | | | |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|--|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 94. | Levenson, V. V., E. D. Transue, and I. B. Roninson. 1998. Internal ribosomal entry site-containing retroviral vectors with green fluorescent protein and drug resistance markers. <i>Hum. Gene Ther.</i> 9:1233-1236. | | |
| | 95. | Li, C., S. Ke, Q. P. Wu, W. Tansey, N. Hunter, L. M. Buchmiller, L. Milas, C. Charnsangavej, and S. Wallace. 2000. Tumor irradiation enhances the tumor-specific distribution of poly(L-glutamic acid)-conjugated paclitaxel and its antitumor efficacy. <i>Clin. Cancer Res.</i> 6:2829-2834. | | |
| | 96. | Li, X., E. M. Eastman, R. J. Schwartz, and R. Draghia-Akli. 1999. Synthetic muscle promoters: activities exceeding naturally occurring regulatory sequences. <i>Nat. Biotechnol.</i> 17:241-245. | | |
| | 97. | Lin, H., K. E. Yutzey, and S. F. Konieczny. 1991. Muscle-specific expression of the troponin I gene requires interactions between helix-loop-helix muscle regulatory factors and ubiquitous transcription factors. <i>Mol. Cell Biol.</i> 11:267-280. | | |
| | 98. | Liu, Y., H. Li, K. Tanaka, N. Tsumaki, and Y. Yamada. 2000. Identification of an enhancer sequence within the first intron required for cartilage-specific transcription of the alpha2(XI) collagen gene. <i>J. Biol. Chem.</i> 275:12712-12718. | | |
| | 99. | Lucas, M. L., L. Heller, D. Coppola, and R. Heller. 2002. IL-12 plasmid delivery by in vivo electroporation for the successful treatment of established subcutaneous B16.F10 melanoma. <i>Mol. Ther.</i> 5:668-675. | | |
| | 100. | Lucas, M. L., M. J. Jaroszeski, R. Gilbert, and R. Heller. 2001. In vivo electroporation using an exponentially enhanced pulse: a new waveform. <i>DNA Cell Biol.</i> 20:183-188. | | |
| | 101. | Macejak, D. G. and P. Sarnow. 1991. Internal initiation of translation mediated by the 5' leader of a cellular mRNA. <i>Nature</i> 353:90-94. | | |
| | 102. | Matsubara, H., Y. Gunji, T. Maeda, K. Tasaki, Y. Koide, T. Asano, T. Ochiai, S. Sakiyama, and M. Tagawa. 2001. Electroporation-mediated transfer of cytokine genes into human esophageal tumors produces anti-tumor effects in mice. <i>Anticancer Res.</i> 21:2501-2503. | | |
| | 103. | Matsu, A., I. Tooyama, S. Isobe, Y. Oomura, I. Akiguchi, K. Hanai, J. Kimura, and H. Kimura. 1994. Immunohistochemical localization in the rat brain of an epitope corresponding to the fibroblast growth factor receptor-1. <i>Neuroscience</i> 60:49-66. | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

| | | | | | |
|--|----|----|-----------|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/764,818 |
| | | | | Filing Date | 01/26/2004 |
| | | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 11 | of | 16 Sheets | Attorney Docket Number | AVSI-0033 (108328.00170) |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|---|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 104. | McNally, M. A., J. S. Lebkowski, T. B. Okarma, and L. B. Lerch. 1988. Optimizing electroporation parameters for a variety of human hematopoietic cell lines. <i>Biotechniques</i> 6:882-886. | | |
| | 105. | Miklavcic, D., K. Beravs, D. Semrov, M. Cemazar, F. Demsar, and G. Sersa. 1998. The importance of electric field distribution for effective in vivo electroporation of tissues. <i>Biophys. J</i> 74:2152-2158. | | |
| | 106. | Miller, K. F., D. J. Bolt, V. G. Pursel, R. E. Hammer, C. A. Pinkert, R. D. Palmiter, and R. L. Brinster. 1989. Expression of human or bovine growth hormone gene with a mouse metallothionein-1 promoter in transgenic swine alters the secretion of porcine growth hormone and insulin-like growth factor-I. <i>J. Endocrinol.</i> 120:481-488. | | |
| | 107. | Mumper, R. J., J. Wang, S. L. Klakamp, H. Nitta, K. Anwer, F. Tagliaferri, and A. P. Rolland. 1998. Protective interactive noncondensing (PINC) polymers for enhanced plasmid distribution and expression in rat skeletal muscle. <i>J. Control Release</i> 52:191-203. | | |
| | 108. | Muramatsu, T., S. Arakawa, K. Fukazawa, Y. Fujiwara, T. Yoshida, R. Sasaki, S. Masuda, and H. M. Park. 2001. In vivo gene electroporation in skeletal muscle with special reference to the duration of gene expression. <i>Int. J Mol. Med.</i> 7:37-42. | | |
| | 109. | Murray, R. D. and S. M. Shalet. 2000. Growth hormone: current and future therapeutic applications. <i>Expert. Opin. Pharmacother.</i> 1:975-990. | | |
| | 110. | Nairn, R. S., G. M. Adair, T. Porter, S. L. Pennington, D. G. Smith, J. H. Wilson, and M. M. Seidman. 1993. Targeting vector configuration and method of gene transfer influence targeted correction of the APRT gene in Chinese hamster ovary cells. <i>Somat. Cell Mol. Genet.</i> 19:363-375. | | |
| | 111. | Narum, D. L., S. Kumar, W. O. Rogers, S. R. Fuhrmann, H. Liang, M. Oakley, A. Taye, B. K. Sim, and S. L. Hoffman. 2001. Codon optimization of gene fragments encoding Plasmodium falciparum merozoite proteins enhances DNA vaccine protein expression and immunogenicity in mice. <i>Infect. Immun.</i> 69:7250-7253. | | |
| | 112. | Neumann, E., M. Schaefer-Ridder, Y. Wang, and P. H. Hofschneider. 1982. Gene transfer into mouse lymphoma cells by electroporation in high electric fields. <i>EMBO J.</i> 1:841-845. | | |
| | 113. | Nomoto, S., Y. Tatematsu, T. Takahashi, and H. Osada. 1999. Cloning and characterization of the alternative promoter regions of the human LIMK2 gene responsible for alternative transcripts with tissue-specific expression. <i>Gene</i> 236:259-271. | | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

| | | | |
|--|----|----|--------------------------|
| Substitute for form 1449A/PTO | | | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | |
| (use as many sheets as necessary) | | | |
| Sheet | 12 | of | 16 Sheets |
| | | | Attorney Docket Number |
| | | | AVSI-0033 (108328.00170) |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|--|-----------------------|---|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 114. | Ohlsson, H., S. Thor, and T. Edlund. 1991. Novel insulin promoter- and enhancer-binding proteins that discriminate between pancreatic alpha- and beta-cells. Mol. Endocrinol. 5:897-904. | | |
| | 115. | Otani, Y., Y. Tabata, and Y. Ikada. 1996. Rapidly curable biological glue composed of gelatin and poly(L-glutamic acid). Biomaterials 17:1387-1391. | | |
| | 116. | Otani, Y., Y. Tabata, and Y. Ikada. 1998. Hemostatic capability of rapidly curable glues from gelatin, poly(L-glutamic acid), and carbodiimide. Biomaterials 19:2091-2098. | | |
| | 117. | Parker, R. Using Body Condition Scoring in Dairy Herd Management. Ontario Ministry of Agriculture and Food Fact Sheet # 94-053. 1996. | | |
| | 118. | Pech, M., C. D. Rao, K. C. Robbins, and S. A. Aaronson. 1989. Functional identification of regulatory elements within the promoter region of platelet-derived growth factor 2. Mol. Cell Biol. 9:396-405. | | |
| | 119. | Pelletier, J. and N. Sonenberg. 1988. Internal initiation of translation of eukaryotic mRNA directed by a sequence derived from poliovirus RNA. Nature 334:320-325. | | |
| | 120. | Pinkert, C. A., D. M. Ornitz, R. L. Brinster, and R. D. Palmiter. 1987. An albumin enhancer located 10 kb upstream functions along with its promoter to direct efficient, liver-specific expression in transgenic mice. Genes Dev. 1:268-276. | | |
| | 121. | Potter, H., L. Weir, and P. Leder. 1984. Enhancer-dependent expression of human kappa immunoglobulin genes introduced into mouse pre-B lymphocytes by electroporation. Proc. Natl. Acad. Sci. U. S. A 81:7161-7165. | | |
| | 122. | Prentice, H., R. A. Kloner, T. Prigozy, T. Christensen, L. Newman, Y. Li, and L. Kedes. 1994. Tissue restricted gene expression assayed by direct DNA injection into cardiac and skeletal muscle. Journal of Molecular & Cellular Cardiology 26:1393-1401. | | |
| | 123. | Pursel, V. G., D. J. Bolt, K. F. Miller, C. A. Pinkert, R. E. Hammer, R. D. Palmiter, and R. L. Brinster. 1990. Expression and performance in transgenic pigs. J. Reprod. Fertil. Suppl 40:235-45:235-245. | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

| | | | | | |
|--|----|----|-----------|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Application Number | 10/764,818 |
| | | | | Filing Date | 01/26/2004 |
| | | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 13 | of | 16 Sheets | Attorney Docket Number | AVSI-0033 (108328.00170) |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|--|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | |
| | 124. | Radke, B. and G. Shook. 2001. Culling and Genetic Improvement Programs For Dairy Herds. In: Food Animal Production Medicine. pp. 291-307. W.B.Saunders Company. | | T ² |
| | 125. | Robbins, K., S. McCabe, T. Scheiner, J. Strasser, R. Clark, and P. Jardieu. 1994. Immunological effects of insulin-like growth factor-I--enhancement of immunoglobulin synthesis. Clin. Exp. Immunol. 95:337-342. | | |
| | 126. | Rodenburg, J. Body Condition Scoring of Cattle. Ontario Ministry of Agriculture and Food Fact Sheet # 92-122. 1996. | | |
| | 127. | Satozawa, N., K. Takezawa, T. Miwa, S. Takahashi, M. Hayakawa, and H. Ooka. 2000. Differences in the effects of 20 K- and 22 K-hGH on water retention in rats. Growth Horm. IGF. Res. 10:187-192. | | |
| | 128. | Skroch, P., C. Buchman, and M. Karin. 1993. Regulation of human and yeast metallothionein gene transcription by heavy metal ions. Prog. Clin. Biol. Res. 380:113-28.:113-128. | | |
| | 129. | Smith, L. C. and J. L. Nordstrom. 2000. Advances in plasmid gene delivery and expression in skeletal muscle. Curr. Opin. Mol. Ther. 2:150-154. | | |
| | 130. | Smith, V. G., A. D. Leman, W. J. Seaman, and F. VanRavenswaay. 1991. Pig weaning weight and changes in hematology and blood chemistry of sows injected with recombinant porcine somatotropin during lactation. J. Anim Sci. 69:3501-3510. | | |
| | 131. | Song, S., J. Embury, P. J. Laipis, K. I. Berns, J. M. Crawford, and T. R. Flotte. 2001. Stable therapeutic serum levels of human alpha-1 antitrypsin (AAT) after portal vein injection of recombinant adeno-associated virus (rAAV) vectors. Gene Ther. 8:1299-1306. | | |
| | 132. | Soubrier, F., B. Cameron, B. Manse, S. Somarriba, C. Dubertret, G. Jaslin, G. Jung, C. L. Caer, D. Dang, J. M. Mouvault, D. Scherman, J. F. Mayaux, and J. Crouzet. 1999. pCOR: a new design of plasmid vectors for nonviral gene therapy. Gene Ther. 6:1482-1488. | | |
| | 133. | Studer, E. 1998. A veterinary perspective of on-farm evaluation of nutrition and reproduction. J Dairy Sci 81:872-876. | | |

| | | |
|--------------------|--|-----------------|
| Examiner Signature | | Date Considered |
|--------------------|--|-----------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

| | | | | | | |
|---|--|----|----|--------------------------|------------------------|--------------------------|
| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Complete if Known | | |
| Sheet | | 14 | of | 16 Sheets | Attorney Docket Number | AVSI-0033 (108328.00170) |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|---|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 134. | Terada, Y., H. Tanaka, T. Okado, S. Inoshita, M. Kuwahara, T. Akiba, S. Sasaki, and F. Marumo. 2001. Efficient and ligand-dependent regulated erythropoietin production by naked dna injection and in vivo electroporation. Am. J Kidney Dis. 38:S50-S53. | | |
| | 135. | Thorner, M. O., L. A. Frohman, D. A. Leong, J. Thominet, T. Downs, P. Hellmann, J. Chitwood, J. M. Vaughan, and W. Vale. 1984. Extrahypothalamic growth-hormone-releasing factor (GRF) secretion is a rare cause of acromegaly: plasma GRF levels in 177 acromegalic patients. Journal of Clinical Endocrinology & Metabolism 59:846-849. | | |
| | 136. | Thorner, M. O., M. L. Hartman, M. L. Vance, S. S. Pezzoli, and E. J. Ampleford. 1995. Neuroendocrine regulation of growth hormone secretion. Neuroscience & Biobehavioral Reviews 19:465-468. | | |
| | 137. | Thorner, M. O., M. L. Vance, W. S. Evans, A. D. Rogol, J. Rivier, W. Vale, Blizzard, and RM. 1986. Clinical studies with GHRH in man. Hormone Research 24:91-98. | | |
| | 138. | Toneguzzo, F., A. Keating, S. Glynn, and K. McDonald. 1988. Electric field-mediated gene transfer: characterization of DNA transfer and patterns of integration in lymphoid cells. Nucleic Acids Res. 16:5515-5532. | | |
| | 139. | Tripathy, S. K., E. C. Svensson, H. B. Black, E. Goldwasser, M. Margalith, Hobart, PM, and J. M. Leiden. 1996. Long-term expression of erythropoietin in the systemic circulation of mice after intramuscular injection of a plasmid DNA vector. Proc. Natl. Acad. Sci. USA 93:10876-10880. | | |
| | 140. | Tronche, F., A. Rollier, I. Bach, M. C. Weiss, and M. Yaniv. 1989. The rat albumin promoter: cooperation with upstream elements is required when binding of APF/HNF1 to the proximal element is partially impaired by mutation or bacterial methylation. Mol. Cell Biol. 9:4759-4766. | | |
| | 141. | Tronche, F., A. Rollier, P. Herbomel, I. Bach, S. Cereghini, M. Weiss, and M. Yaniv. 1990. Anatomy of the rat albumin promoter. Mol. Biol. Med. 7:173-185. | | |
| | 142. | Trudel, M. and F. Costantini. 1987. A 3' enhancer contributes to the stage-specific expression of the human beta-globin gene. Genes Dev. 1:954-961. | | |
| | 143. | Tsumaki, N., T. Kimura, K. Tanaka, J. H. Kimura, T. Ochi, and Y. Yamada. 1998. Modular arrangement of cartilage- and neural tissue-specific cis-elements in the mouse alpha2(XI) collagen promoter. J. Biol. Chem. 273:22861-22864. | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

15

of

16 Sheets

Complete if Known

| | |
|----------------------|-------------------------------|
| Application Number | 10/764,818 |
| Filing Date | 01/26/2004 |
| First Named Inventor | Ruxandra Draghia-Akli, et al. |
| Group Art Unit | |
| Examiner Name | |

Attorney Docket Number AVSI-0033 (108328.00170)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---------------------|-----------------------|--|----------------|
| | 144. | Tsunekawa, B., M. Wada, M. Ikeda, H. Uchida, N. Naito, and M. Honjo. 1999. The 20-kilodalton (kDa) human growth hormone (hGH) differs from the 22-kDa hGH in the effect on the human prolactin receptor. <i>Endocrinology</i> 140:3909-3918. | |
| | 145. | Tsurumi, Y., S. Takeshita, D. Chen, M. Kearney, S. T. Rossow, J. Passeri, J. R. Horowitz, J. F. Symes, and J. M. Isner. 1996. Direct intramuscular gene transfer of naked DNA encoding vascular endothelial growth factor augments collateral development and tissue perfusion [see comments]. <i>Circulation</i> 94:3281-3290. | |
| | 146. | Tur-Kaspa, R., L. Teicher, B. J. Levine, A. I. Skoultchi, and D. A. Shafritz. 1986. Use of electroporation to introduce biologically active foreign genes into primary rat hepatocytes. <i>Mol. Cell Biol.</i> 6:716-718. | |
| | 147. | Vance, M. L. 1990. Growth-hormone-releasing hormone. [Review] [52 refs]. <i>Clinical Chemistry</i> 36:415-420. | |
| | 148. | Vance, M. L., D. L. Kaiser, W. S. Evans, R. Furlanetto, W. Vale, J. Rivier, and M. O. Thorner. 1985. Pulsatile growth hormone secretion in normal man during a continuous 24-hour infusion of human growth hormone releasing factor (1-40). Evidence for intermittent somatostatin secretion. <i>J. Clin. Invest.</i> 75:1584-1590. | |
| | 149. | Verhelst, J., R. Abs, M. Vandeweghe, J. Mockel, J. J. Legros, G. Copinschi, C. Mahler, B. Velkeniers, L. Vanhaelst, A. Van Aelst, D. De Rijdt, A. Stevenaert, and A. Beckers. 1997. Two years of replacement therapy in adults with growth hormone deficiency. <i>Clin. Endocrinol. (Oxf)</i> 47:485-494. | |
| | 150. | Vilquin, J. T., P. F. Kennel, M. Patureau-Jouas, P. Chapdelaine, N. Boissel, P. Delaere, J. P. Tremblay, D. Scherman, M. Y. Fiszman, and K. Schwartz. 2001. Electrotransfer of naked DNA in the skeletal muscles of animal models of muscular dystrophies. <i>Gene Ther.</i> 8:1097-1107. | |
| | 151. | Vittone, J., M. R. Blackman, J. Busby-Whitehead, C. Tsiao, K. J. Stewart, J. Tobin, T. Stevens, M. F. Bellantoni, M. A. Rogers, G. Baumann, J. Roth, S. M. Harman, and R. G. S. Spencer. 1997. Effects of single nightly injections of growth hormone-releasing hormone (GHRH 1-29) in healthy elderly men. <i>Metabolism: Clinical and Experimental</i> 46:89-96. | |
| | | | |
| | | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

| | | | | | |
|--|----|----|-----------|--------------------------|-------------------------------|
| Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/764,818 |
| (use as many sheets as necessary) | | | | Filing Date | 01/26/2004 |
| | | | | First Named Inventor | Ruxandra Draghia-Akli, et al. |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 16 | of | 16 Sheets | Attorney Docket Number | AVSI-0033 (108328.00170) |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | |
|--|-----------------------|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | 152. | Wada, M., H. Uchida, M. Ikeda, B. Tsunekawa, N. Naito, S. Banba, E. Tanaka, Y. Hashimoto, and M. Honjo. 1998. The 20-kilodalton (kDa) human growth hormone (hGH) differs from the 22-kDa hGH in the complex formation with cell surface hGH receptor and hGH-binding protein circulating in human plasma. Mol. Endocrinol. 12:146-156. | |
| | 153. | Wells, K. E., J. Maule, R. Kingston, K. Foster, J. McMahon, E. Damien, A. Poole, and D. J. Wells. 1997. Immune responses, not promoter inactivation, are responsible for decreased long-term expression following plasmid gene transfer into skeletal muscle. FEBS Lett. 407:164-168. | |
| | 154. | Wolff, J. A., R. W. Malone, P. Williams, W. Chong, G. Acsadi, A. Jani, Felgner, and PL. 1990. Direct gene transfer into mouse muscle in vivo. Science 247:1465-1468. | |
| | 155. | Wu, H. K., J. A. Squire, Q. Song, and R. Weksberg. 1997. Promoter-dependent tissue-specific expressive nature of imprinting gene, insulin-like growth factor II, in human tissues. Biochem. Biophys. Res. Commun. 233:221-226. | |
| | 156. | Xie, T. D. and T. Y. Tsong. 1993. Study of mechanisms of electric field-induced DNA transfection. V. Effects of DNA topology on surface binding, cell uptake, expression, and integration into host chromosomes of DNA in the mammalian cell. Biophys. J. 65:1684-1689. | |
| | 157. | Yasui, A., K. Oda, H. Usunomiya, K. Kakudo, T. Suzuki, T. Yoshida, H. M. Park, K. Fukazawa, and T. Muramatsu. 2001. Elevated gastrin secretion by in vivo gene electroporation in skeletal muscle. Int. J. Mol. Med. 8:489-494. | |
| | 158. | Yin, D. and J. G. Tang. 2001. Gene therapy for streptozotocin-induced diabetic mice by electroporational transfer of naked human insulin precursor DNA into skeletal muscle in vivo. FEBS Lett. 495:16-20. | |
| | 159. | Yorifuji, T. and H. Mikawa. 1990. Co-transfer of restriction endonucleases and plasmid DNA into mammalian cells by electroporation: effects on stable transformation. Mutat. Res. 243:121-126. | |
| | 160. | Yutzey, K. E. and S. F. Konieczny. 1992. Different E-box regulatory sequences are functionally distinct when placed within the context of the troponin I enhancer. Nucleic Acids Res. 20:5105-5113. | |
| | 161. | Zhao-Emonet, J. C., O. Boyer, J. L. Cohen, and D. Klatzmann. 1998. Deletional and mutational analyses of the human CD4 gene promoter: characterization of a minimal tissue-specific promoter. Biochim. Biophys. Acta 1442:109-119. | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.